Decision Memo for Cardiac Rehabilitation Programs (CAG-00089R2)

Decision Summary

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. No. 110-275) amended Title XVIII of the Social Security Act, in pertinent part, to provide for coverage of cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) under Medicare Part B. The statute specifies certain conditions for these services, with coverage to begin on January 1, 2010. The Secretary published a notice of proposed rulemaking (74 Fed. Reg. 33, 520) on July 13, 2009. After considering public comments, the Secretary issued a final rule on November 25, 2009. (74 Fed. Reg. 61,738, 62,004). This rule was effective on January 1, 2010.

In order to ensure consistency with the statute and regulations, the Centers for Medicare and Medicaid Services (CMS) has decided to repeal section 20.10 from the Medicare National Coverage Determination (NCD) Manual (Pub. 100-03).

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Decision Memo

TO: Administrative File: CAG-00089R2

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SUBJECT: Coverage Decision Memorandum for Cardiac Rehabilitation Programs

DATE: February 22, 2010

I. Decision

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. No. 110-275) amended Title XVIII of the Social Security Act, in pertinent part, to provide for coverage of cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) under Medicare Part B. The statute specifies certain conditions for these services, with coverage to begin on January 1, 2010. The Secretary published a notice of proposed rulemaking (74 Fed. Reg. 33, 520) on July 13, 2009. After considering public comments, the Secretary issued a final rule on November 25, 2009. (74 Fed. Reg. 61,738, 62,004). This rule was effective on January 1, 2010.

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II. Background

Cardiac rehabilitation (CR) developed in the 1950s from the concept of early mobilization after acute myocardial infarction (Pashkow, 1993). The standard of care prior to the widespread adoption of CR was bedrest and inactivity after acute myocardial infarction (Forman, et al., 2000).In the 1970s, cardiac rehabilitation developed into highly structured, physician supervised, electrocardiographically-monitored exercise programs. However, the programs consisted almost solely of exercise alone (Ades, et al., 2000). Foreman et al. (2000) states that "over subsequent years, CR broadened beyond exercise into a composite of cardiac risk modification. Lipid, blood pressure and stress reductions, smoking cessation, diet change, and weight loss were coupled to goals of exercise training."

III. History of Medicare Coverage

Since 1982, Medicare has covered, under an NCD, CR for patients who experience stable angina, have had coronary artery bypass grafts, or have had an acute myocardial infarction within the past 12 months. Effective March 22, 2006, we modified the NCD to cover comprehensive CR programs for patients who experience one of the following.

- A documented diagnosis of acute myocardial infarction within the preceding 12 months.

- A coronary bypass surgery.
- Stable angina pectoris.
- A heart valve repair/replacement.
- A percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting.
- A heart or heart-lung transplant.

Comprehensive programs must include a medical evaluation, a program to modify cardiac risk factors, prescribed exercise, education, and counseling and may last for up to 36 sessions over 18 weeks or no more than 72 sessions over 36 weeks if determined appropriate by the local Medicare contractors. Facilities furnishing CR must have immediately available necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment and be staffed with personnel necessary to conduct the program safely and effectively who are trained in advanced life support techniques and exercise therapy for coronary disease. The program must also be under the direct supervision of a physician.

IV. Timeline of Recent Activities

July 13, 2009	Notice of Proposed Rulemaking- CMS announced at 74 Fed. Reg. at 33, 606 that "[w]hen the rulemaking is completed, we will take the necessary steps to withdraw and/or modify the NCD."
October 30, 2009	CY 2010 Physician Fee Schedule Final Rule with Comment Period displayed online (http://federalregister.gov/OFRUpload/OFRData/2009-26502_PI.pdf).
November 25, 2009	CMS internally generates a reconsideration with the release of the proposed decision memorandum. 30-day public comment period begins.

V. Regulation Providing for Cardiac Rehabilitation Coverage

As noted earlier, section 144(a) of MIPPA established coverage for CR and ICR programs. To implement the statute, CMS is adding a new section (42 C.F.R. §410.49), *Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage*, to the Code of Federal Regulations. This section was put on display Friday October 30, 2009 (available at http://federalregister.gov/OFRUpload/OFRData/2009-26502_PI.pdf). The Final Rule was published in the Federal Register on November 25, 2009, and the coverage requirements were effective January 1, 2010.

VI. Public Comments

During the 30 day public comment period following the release of the proposed decision memorandum, CMS received five comments. The comments are summarized below, followed by CMS responses to the comments.

Comments:
Two commenters support the proposed decision to repeal the NCD in light of the changes to the statute and regulations.

Response:
We agree with the comments that recognize that the previous NCD is obsolete and that repealing the NCD will eliminate public confusion.

Comments:
Two commenters contend that the NCD should not be repealed and instead CMS should use the NCD to clarify that CR services may be provided in Critical Access Hospitals (CAHs) and, based upon regulations specific to CAHs, physicians are not required to provide direct supervision.

Response:
CMS has decided to finalize the proposed decision to repeal section 20.10 of the Medicare NCD Manual.

Issues surrounding CR services performed in CAHs are beyond the scope of this analysis. CMS proposed rules with respect to the implementation section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 on July 13, 2009. 74 Fed. Reg. 33520. The public comment period on the notice of proposed rulemaking ended on August 31, 2009. Our final rules were effective on January 1, 2010. A national coverage determination is not the appropriate vehicle to change the substance of a final rule. CMS may consider the issues raised by the commenters in future rulemaking.

We note, however, that both the statute (section 1861(eee)(1)) and our regulations (410.49(a)) define a CR program as a "physician-supervised program."Because the Congress explicitly stated that services must be "physician-supervised," non-physician practitioners may not serve the supervising role for CR services even if those practitioners may sometimes supervise other services in other settings under separate legal authority.

Comment*:*
One commenter asserts that Medicare should pay for CR and that physicians should determine the time period over which services are provided.

Response:
Medicare has established coverage for CR through rulemaking as described in section V of this document. Physicians may determine the time period over which CR services are provided as long as it falls within the covered time period identified in the regulation. The regulation allows for coverage of up to 36 1- hour sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare contractor. Physicians retain significant discretion to design the individualized treatment plan and to tailor the component services to meet the individual's needs.

VII. Assessment

We have decided to repeal section 20.10 of the Medicare NCD Manual. As such, the NCD is no longer in effect and will be removed from the NCD manual.

VIII. Conclusion

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. No. 110-275) amended Title XVIII of the Social Security Act, in pertinent part, to provide for coverage of cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) under Medicare Part B. The statute specifies certain conditions for these services, with coverage to begin on January 1, 2010. The Secretary published a notice of proposed rulemaking (74 Fed. Reg. 33, 520) on July 13, 2009. After considering public comments, the Secretary issued a final rule on November 25, 2009. (74 Fed. Reg. 61,738, 62,004). This rule was effective on January 1, 2010.

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